Remarks

The various parts of the Office Action (and other matters, if any) are discussed below under appropriate headings.

Telephone Interview Summary

The undersigned would once again like to thank Examiner Elmer Chao for his courtesy during a telephone interview on November 15, 2007. During the telephone interview, Examiner Chao and the undersigned engaged in discussions along the lines summarized below.

Drawings

The drawings were objected to for containing "hand-written numerals and text." A replacement drawing sheet has been provided. No new matter is contained in the replacement drawing sheet.

New Matter Objection

The amendment filed on February 22, 2007 was objected to because it allegedly introduces new matter into the disclosure. In particular, the Office Action alleged that the subject matter "before infusion of a fluid into the tissue," which was added to claims 1 and 18 is not directly supported by the original disclosure. As was discussed with the Examiner by phone, this subject matter is included in the disclosure, e.g., on page 2, lines 25-27, and on page 3, lines 7-10. In light of the foregoing, the objection under 35 U.S.C. § 132(a) should be withdrawn.

Claim Rejections - 35 USC § 101

Claim 16 was rejected because its form was inconsistent with that required for statutory subject matter. The claim has been amended to include a form consistent with statutory subject matter. Therefore, the rejection should be withdrawn.

Claim Rejections - 35 USC § 102 and § 103

Claim 1 has been amended to more clearly define patentably over the references applied by the Examiner. Claim 1, as amended, recites a method for identifying advantageous and non-advantageous infusion regions in a tissue that includes, *inter alia*, capturing via an imaging system functional anatomical data and/or structural anatomical data before infusion of a fluid into the tissue, evaluating the captured functional and/or structural anatomical data with computer assistance and without use of an infusion fluid, and based on the evaluating step, identifying directional

channels within the tissue and determining infusion distribution information related to the identified directional channels.

The claimed invention facilitates the identification of advantageous and/or non-advantageous infusion regions based on a capture and evaluation of functional and/or structural before infusion of a fluid into the tissue. The functional and/or structural anatomical data is evaluated without use of an infusion fluid to identify directional channels and/or associated infusion distribution information before infusion fluid is introduced into the tissue.

In contrast, Kucharczyk '316 is not understood to disclose or fairly suggest capturing functional and/or structural anatomical data before infusion of a fluid into the tissue and evaluating the captured functional and/or structural anatomical data with computer assistance and without use of an infusion fluid. Further, Kucharczyk '316 is not understood to disclose or fairly suggest identifying directional channels and related infusion distribution information based on evaluation of anatomical data that is captured before any infusion fluid is introduced into the tissue.

As understood, Kucharczyk is concerned with tracking the location of <u>delivered</u> materials – i.e., imaging and tracking fluids <u>after they are infused</u> into a patient.¹ By infusing the fluid, and then tracking and/or imaging the already-infused fluid, Kucharczyk '316 cannot reasonably be interpreted to disclose the method recited in amended claim 1.

Neither Gillies et al. nor Strommer et al. cure the deficiencies of Kucharczyk '316 with respect to amended claim 1. For at least these reasons, the rejection of claim 1 and claims 2-16 and 21 should be withdrawn.

Claim 18, as amended, recites a device for assisting planning for introducing an infusion fluid into regions of the brain that includes, *inter alia*, an imaging device that captures functional and/or structural anatomical data <u>before an infusion of fluid into regions of the brain</u>, and a processor that is programmed to perform and assist in evaluating the functional and/or structural anatomical data in order to identify directional channels within the regions of the brain and determine infusion distribution information related to the identified directional channels, where the directional channels and infusion distribution information are indicative of advantageous and non-advantageous infusion regions.

The claimed processor also <u>produces and evaluates a distribution simulation</u> <u>apart from regions of the brain before the infusion fluid is infused</u>, the distribution

¹ Kucharczyk '316 includes many passages consistent with this understanding. See, e.g., col. 7, In 8-10, col. 7, In. 45-55, col. 8, In. 12-15, col. 8, In. 57-61, col. 11, In. 13-18.

simulation being indicative of an infusion fluid when it is introduced at particular points, on the basis of the captured anatomical data.

Kucharczyk '316, taken alone or in combination with Gilles et al. and/or Strommer et al. fails to disclose or fairly suggest a processor that is programmed to produce and evaluate a distribution simulation apart from regions of the brain before the infusion fluid is infused, where the distribution simulation being indicative of an infusion fluid when it is introduced at particular points, on the basis of the captured anatomical data.

Therefore, it is respectfully submitted that the rejections of claim 18 and dependent claims 19-20 should be withdrawn.

New claim 22 recites a method for identifying advantageous and non-advantageous infusion regions in a tissue that includes, *inter alia*, capturing via an imaging system functional anatomical data and/or structural anatomical data <u>before infusion of any infusion fluid into the tissue</u>, evaluating the captured functional and/or structural anatomical data with computer assistance, and based on the evaluating step, identifying directional channels within the tissue and determining infusion distribution information related to the identified directional channels.

As is discussed above, Kucharczyk '316 has not been found to disclose or fairly suggest the claimed method, including capturing via an imaging system functional anatomical data and/or structural anatomical data <u>before infusion of any infusion fluid into the tissue</u>. In contrast, Kucharczyk '316 is understood to disclose tracking the location of delivered materials – i.e., imaging and tracking fluids *after they are infused* into a patient.

Therefore, it is respectfully submitted that new claim 22 is in condition for allowance.

Telephone Interview

In the interests of advancing this application to issue and compact prosecution, it is respectfully requested that the Examiner telephone the undersigned to discuss any of the foregoing with which there may be some controversy or confusion or to make any suggestions that the Examiner may have to place the application in condition for allowance.

Conclusion

In view of the foregoing, request is made for timely issuance of a notice of allowance.

Respectfully submitted,

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